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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,149	12/12/2003	Chung Chan	02-12	2580

10117 7590 08/22/2006

ZYMOGENETICS, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
1201 EASTLAKE AVENUE EAST  
SEATTLE, WA 98102-3702

EXAMINER
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JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,149	<b>Applicant(s)</b> CHAN ET AL.	
	<b>Examiner</b> Dong Jiang	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
4a) Of the above claim(s) 7-21 is/are withdrawn from consideration.  
5) ☒ Claim(s) 1 and 2 is/are allowed.  
6) ☒ Claim(s) 3-6 and 22 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### DETAILED OFFICE ACTION

Applicant's election of Group I invention filed on 16 June 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Currently, claims 1-22 are pending, and claims 1-6 and 22 are under consideration. Claims 7-21 are withdrawn from further consideration as being drawn to a non-elected invention.

#### **Formal Matters:**

##### ***Priority acknowledgement***

This application claims benefit of U.S. provisional applications 60/433,448 filed on 12/13/02, and 60/433,452 filed on 12/13/02, which is acknowledged.

##### ***Sequences***

This application is objected to because it does not include the statement "the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing" and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). **Correction is required.**

##### ***Drawings***

This application lacks formal drawing. The informal drawing filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

##### ***Claims***

Claim 6 is objected to for the following informalities, appropriate correction is required for each item:

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Claim 6, line 1, "IL-21 protein" is suggested to replace "IL-21 proteins".

**Rejections under 35 U.S.C. 112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Claims 3 and 22 recite a deposit of an expression vector in ATCC Deposit Designation PTA-4853. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112.

For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository. (See MPEP 2404-2410.02)

**If a deposit is made under the terms of the Budapest Treaty**, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

- (a) that the deposit has been made under the terms of the Budapest Treaty; **and**
- (b) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be *irrevocably removed* upon the granting of a patent,

would satisfy the deposit requirements. See 37 C.F.R. 1.808.

**If a deposit is not made under the terms of the Budapest Treaty**, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and establishing that the following criteria have been met:

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- (a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807 is provided; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination, or loss of capability to function described in the manner in the specification.

**In either case**, the identifying information set forth in 37 C.F.R. 1.809(d) should be added to the specification if it is not already present. For deposits made with the ATCC, note that effective 23 March 1988 the depository's address is:

American Type Culture Collection  
10801 University Boulevard  
Manassas, VA 20110-2209

See 37 C.F.R. 1.803-1.809 for additional explanation of these requirements.

Furthermore, claim 22 also recites "a host cell strain of zGOLD1, deposited with the ATCC, ...", however, there is no deposit number or designation for the specific host strain of "zGOLD1". The specification does not provide the deposit information ("undesignated at filing time", page 64, line13), nor the statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent, and the biological material is required to practice the instant invention. In addition, host cell strain of "zGOLD1" does not seem to be commercially available. As such, one skilled in the art would not be able to make or use the claimed invention. The enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material, *and* a statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. See 37 CFR 1.802.

**Prior Art:**

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Novak et al. (US6,307,024) discloses a nucleic acid, which nucleotide sequence, SEQ ID NO:1, is 74% identical to the present SEQ ID NO:27 (see computer printout of the search results), and encodes a polypeptide, zalpha11 of SEQ ID NO:2. Novak's zalpha11 of SEQ ID NO:2 comprises the present SEQ ID NO:28 with 99.3% sequence identity (see computer printout of the search results).

**Conclusion:**

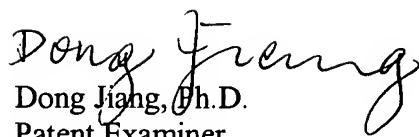
Claims 1 and 2 are allowable.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Dong Jiang, Ph.D.  
Patent Examiner

AU1646

8/10/06